



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

April 4, 2019

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MEMORANDUM

SUBJECT: Review of Benefits and a Resistance Management Plan for a New Premix Herbicide Product, Dicamba (diglycolamine salt) + s-Metolachlor, for Use on Dicamba-Tolerant Cotton and Soybean (PC# 0128931 and 108800, DP# 450536 & 450508)

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PEER REVIEW PANEL: March 13, 2019

INTRODUCTION

Syngenta submitted an application to register Tavium®, a premixed product of dicamba (diglycolamine salt) (Group 4) and s-metolachlor (Group 15) on genetically modified dicamba-tolerant cotton and soybean. The proposed application time of the premix would be for use as a preemergence herbicide (to the crop) and as an over-the-top application (postemergence to the crop) for dicamba-tolerant cotton and soybean. The Registration Division requested that Biological and Economic Analysis Branch (BEAD) review the benefits to the grower and herbicide resistance management plan of the premix product.

BEAD reviewed the information provided by the registrant about the differences in the use parameters between the premix and over-the-top dicamba-only products and s-metolachlor-only products (Syngenta 2019c). The registrant also submitted information on the benefits of the premixed product compared to dicamba-only products (Syngenta 2019a, 2019b, 2019c).

However, because existing registrations of over-the-top dicamba-only products can be tank mixed with s-metolachlor, BEAD considers the appropriate evaluation is to compare the requested premix with a tank mix of dicamba and s-metolachlor. BEAD relied on previous benefits assessments of over-the-top dicamba-only products (EPA 2018a, Yourman and Chism 2016). The registrant did not provide information beyond pest spectrum on s-metolachlor to support their benefits claims.

BEAD reviewed the herbicide resistance management plan for the premix product provided by Syngenta (Syngenta 2019d) and compared it with the existing resistance management plans for currently registered over-the-top dicamba-only products (EPA 2018b, 2018c). This review only addresses the dicamba component of the premix; Syngenta did not submit a resistance management plan for s-metolachlor. BEAD also reviewed the proposed premix label to ensure that the label had the recommended herbicide resistance management elements according to PRN 2017-1 (EPA 2017a).

BENEFITS

In 2016 and 2018, the Agency found that the main benefit of postemergence over-the-top dicamba-only applications was that they provided dicamba-tolerant soybean and cotton growers with another active ingredient to manage difficult to control broadleaf weeds during the crop growing season, especially glyphosate-resistant weeds (EPA 2018b, Yourman and Chism, 2016). Additionally, in 2018, the Agency found that dicamba, when used as part of a season-long weed management program, could help delay the evolution of resistance to other herbicides (EPA 2018a).

Syngenta claims the premix product controls a broader spectrum of weeds and is better for resistance management because it provides two modes of action when compared to dicamba-only. However, BEAD determined that the appropriate comparison was to the tank mix of dicamba and s-metolachlor. BEAD finds that the benefits of the premix is similar to the use of the tank mix of dicamba and s-metolachlor in regard to pest spectrum and resistance management, given that the premix and tank mix both have the same two modes of action.

Syngenta claims that the premix product provides convenience to the applicator/grower by having two active ingredients in a single container. However, the registrant did not provide evidence that the premix product provides additional benefits over the use of combinations of products containing the single active ingredients. BEAD finds that users of the premix product will have less flexibility as compared with users of a tank mix of dicamba and s-metolachlor because of the differences in use parameters between the premix product and the individual products. Appendix A provides a summary table of the differences in use parameters. Each is discussed in more detail below.

BEAD found that users of the premix product may have a shorter application window for both cotton and soybean than if a tank mix was used. The premix will allow applications to be made to cotton through the 6-leaf stage (approximately 30-35 days after emergence) and 4-leaf stage in soybeans (approximately 21-28 days after emergence) (Syngenta 2019c). When applied as a tank mix, dicamba is the more restrictive active ingredient of the two and defines the use parameters

based on the growth stage or days after planting depending on which criteria is met first. For cotton, growers can apply through mid-bloom stage or up to 60 days after planting. For soybean applications, growers can make applications through R1 (first flower stage) to 45 days after planting.

Syngenta claims that the premix product provides convenience to the applicator/grower by having two active ingredients in a single container. BEAD finds that, if the full single preemergence application rate of the premixed product is applied, it will contain a less than the full permitted single application rate of s-metolachlor and dicamba, if they were applied in a tank mix. Additionally, BEAD finds that, if the full single postemergence application rate of the premixed product is applied, it will contain a maximal single rate of dicamba but less than the full permitted application rate of s-metolachlor. If growers need the full application rate of s-metolachlor for either application timing, they would need to use an additional product which reduces the convenience of a single container by needing additional containers of s-metolachlor. Additionally, BEAD finds that, if the full single application rate of the premixed product is applied twice as the label allows, it will contain a less than the full permitted annual application rate of s-metolachlor and dicamba, if they were applied in a tank mix. If growers need the full annual application rate of s-metolachlor or dicamba, the convenience of a single container is lost because additional containers of s-metolachlor and dicamba would be needed.

The premix may not be applied over-the-top to double-cropped soybeans, whereas a tank mix of dicamba and s-metolachlor can be applied to double-cropped soybean. However, s-metolachlor, as a tank mix partner, has some rotational crop restrictions that may preclude the use in double-cropped soybeans, depending on the crop to be grown in the field and when the crop will be planted.

HERBICIDE RESISTANCE MANAGEMENT PLAN

BEAD reviewed the submitted herbicide resistance management plan (Syngenta 2019d) and compared it with resistance management plans for currently registered over-the-top dicamba products (EPA 2018b, 2018c). BEAD found that the resistance management plan for the premix product was identical to the herbicide resistance management plan for existing over-the-top dicamba products. Syngenta did not submit a resistance management plan for s-metolachlor.

Additionally, BEAD reviewed the proposed label to ensure all elements of the PRN 2017-1 & 2 were addressed (EPA 2017a, 2017b) for both active ingredients. BEAD found some differences in some label elements. Each element is discussed in more detail below.

Elements for Label

1. *Place the MOA using the WSSA Groupings (as described in PRN 2017-01 [EPA 2017a]) on the label.*

This information is provided on the proposed label for both active ingredients.

2. *Clearly express all currently required application parameters and product information on the label, including: single, seasonal (as appropriate), and annual maximum applications rates; the number of seasonal and annual applications permitted; minimum reapplication interval; and amount(s) of active ingredient(s) per pound or gallon (as appropriate).*

Information about the single and annual maximum application rates for both active ingredients is included on the proposed label.

3. *Recommendation (not requirement) that the label should provide information stating that a field should be scouted both before and after a pesticide application.*

The registrant recommends scouting before and after application on the proposed label.

4. *Label statement defining suspected resistance using WSSA (Norsworthy et al. 2012) definition.*

This element is included on the proposed label. The herbicide resistance management plan also provides Syngenta's plan describing how they will investigate suspected resistance.

5. *Label statement that the user should report lack of performance to the registrant or their representative and proactively take action before escaped weeds become widespread in their fields.*

This information is included on the proposed label.

6. *Label statements describing best management practices for resistance management based on PRN 2017-01 [EPA 2017a], Best Management Practices from Weed Science Society of America (Norsworthy et al. 2012) & Herbicide Resistance Action Committee (HRAC 2019).*

This information is included on the proposed label and in the herbicide resistance management plan.

7. *Label statements prompting users to seek information about herbicide resistance in their area and determine if there are local recommendations for adequate control of target weeds.*

This information is included on the proposed label.

Elements for Registrant Actions

8. *Registrant(s) report new cases of suspected and confirmed resistance to EPA and users yearly.*

The herbicide resistance management plan indicates that Syngenta will comply with the 6(a)(2) reporting of adverse effects.

9. *Unique terms and conditions of registration.*

All terms of registration for each active ingredient should apply to premix.

Elements for Education, Training and Stewardship

10. *Provide educational and training materials for growers and users.*

Examples of this information were provided to the Agency, indicating that materials will be made available to growers.

CONCLUSIONS

BEAD finds the overall benefits of the premix to be similar to the tank mixed active ingredients in that it provides two modes of action. However, BEAD found that users of the premix product will likely have less flexibility due to:

- Users of the premix product may have a shorter application window for both cotton and soybean.
- The convenience of a single container is likely lost when growers need to apply additional s-metolachlor-only or dicamba-only products if the maximum single or annual rates of either premix component are needed.
- The premix may not be applied over-the-top to double-cropped soybeans, whereas a tank mix of dicamba and s-metolachlor products can be applied, depending on selection of rotational crops.

The resistance management plan was identical to plans developed by Bayer for XtendiMax® With VaporGrip® (EPA 2018b) and BASF for Engenia (EPA 2018c) for dicamba use on dicamba-tolerant cotton and soybean. The plan does not provide information specific to managing resistance to s-metolachlor.

The registrant addressed the all elements of PRN 2017-1 & 2 (EPA 2017a, 2017b) on the proposed label.

REFERENCES

- EPA. 2017a. Pesticide Registration Notice 2017-1 Guidance for Pesticide Registrants on Pesticide Resistance Management Labeling. Available at: <https://www.epa.gov/sites/production/files/2017-09/documents/prn-2017-1-pesticide-resistance-management-labeling.pdf>
- EPA. 2017b. Pesticide Registration Notice 2017-2: Guidance for Herbicide-Resistance Management, Labeling, Education, Training, and Stewardship. Available at: <https://www.epa.gov/sites/production/files/2017-09/documents/prn-2017-2-herbicide-resistance-management.pdf>
- EPA 2018a. Over-the-top dicamba products for genetically modified cotton and soybeans: benefits and impacts. Available at: <https://www.regulations.gov/document?D=EPA-HQ-OPP-2016-0187-0966>.
- EPA 2018b. Notice of Conditional Registration and Approved Master Label for EPA Registration No. 524-617, Primary Brand Name: M1768 Herbicide Alternate Brand Name: XtendiMax® With VaporGrip® Technology <https://www.regulations.gov/document?D=EPA-HQ-OPP-2016-0187-0971>
- EPA 2018c. Notice of Conditional Registration EPA Registration Number 7969-345 Engenia Herbicide Decision No. 544935 and Approved Label. <https://www.regulations.gov/document?D=EPA-HQ-OPP-2016-0187-0970>
- Syngenta. 2019a. Benefits Summary Tavium® Plus VaporGrip™ Technology. Material submitted as part of the registration.
- Syngenta. 2019b. Benefits of Tavium® Plus VaporGrip® Technology herbicide: Syngenta response and clarifications to EPA questions. Follow-up communication with the Agency in response to questions.
- Syngenta. 2019c. Tavium® Plus VaporGrip® Technology Herbicide Benefits Overview. Follow-up communication with the Agency in response to questions.
- Syngenta. 2019d. Submission of Proposed Herbicide Resistance Management Plan Supporting the Registration of Tavium® Plus VaporGrip® Technology Herbicide (EPA Reg. No. 100-RAEG). Material submitted as part of the registration. Yourman, L., and B. Chism. 2016. Review of Benefits as Described by the Registrant of Dicamba Herbicide for Postemergence Applications to Soybean and Cotton and Addendum Review of the Resistance Management Plan as Described by the Registrant of Dicamba Herbicide for Use on Genetically Modified Soybean and Cotton. U.S. Environmental Protection Agency.

Appendix A. Comparison of use parameters of the premix to individual active ingredients for use on dicamba tolerant cotton and soybean (adapted from Syngenta 2019c).

Use Pattern	Parameter	Premix: dicamba + s-metolachlor (Tavium (100-RAEG))	Dicamba (Xtendimax 524-617)	S-metolachlor (Dual Magnum 100-816)
PRE-Emergent	Application Timing	Preplant, At-Planting, and Preemergence	Burndown/Early Preplant, Preplant, At- Planting, and Preemergence	Preplantand Preemergence
	Maximum single application rate	0.5 lb. a.e. dicamba/A + 1.0 lb S-metolachlor/A	1.0 lb. a.e. dicamba/A	1.25 lb. a.i. s-metolachlor/A
	Maximum annual application rate for Preemergence applications	0.5 lb. a.e. dicamba/A + 1.0 lb S-metolachlor/A	1.0 lb. a.e. dicamba/A	1.25 lb. a.i. s-metolachlor/A
In-crop (post-emergent)	Soybean Application Timing	In-crop applications can be made through V4 soybeans or within 45 days after planting, whichever comes first. No in-crop applications can be made to double crop soybeans	In-crop applications of this product can be made prior to beginning bloom (R1 stage soybeans) or no more than 45 days after planting, whichever occurs first.	In-crop applications can be made preplant through 90 days before harvest
	Cotton Application Timing	In crop applications can be made through 6-leaf cotton or within 60 days after planting, whichever comes first.	In-crop applications of this product can be made up to mid-bloom stage or no more than 60 days after planting, whichever occurs first.	In-crop over-the-top applications can be made preplant through 100 days before harvest and directed applications can be made preplant through 80 days before harvest
	Maximum in-crop applications (post-emergent) single application rate:	0.5 lb. a.e. dicamba/A + 1.0 lb S-metolachlor/A	0.5 lb. a.e. dicamba/A	1.25 lb. a.i. s-metolachlor/A

	Maximum annual application rate for in-crop applications (post-emergent)	0.5 lb. a.e. dicamba/A + 1.0 lb S-metolachlor/A	1.0 lb. a.e. dicamba/A	1.25 lb. a.i. s-metolachlor/A
Full season use (pre and post)	Number of applications allowed at full single application rate (pre and post) in a season	2	3	2
	Total amount of active ingredient/acid equivalent applied (pre and post) in a season	1.0 lb. a.e. dicamba/A + 2.0 lb a.i. S-metolachlor/A	2.0 lb. a.e. dicamba/A	2.5 lb. a.i. s-metolachlor/A